



CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2000-DT-41

September 13, 2000

Richard Beeler, M.D.
Radiologist
St. Vincent Frankfort Hospital
1300 S. Jackson
Frankfort, IN 46041

Dear Dr. Beeler:

We are writing you because on August 31, 2000, your facility was inspected by a representative of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Level 1 finding at your facility:

1. Mammography phantom QC films and records were missing for [REDACTED] weeks. The MQSA Final Rules [21 CFR Part 900.12 (e)(2)] require that an image quality test be conducted at least weekly.

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to placing your facility under a Directed Plan of Correction, charging your facility for the cost of onsite monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with MQSA standards,

suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It was also noted during this inspection that the processor QC testing "aims" values have been reset by re-averaging on a frequent basis and this practice may not be appropriate dependent on the reason for out of limit QC values. We suggest that you consult with your physicist regarding the appropriateness of this re-averaging practice.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Level 1 violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

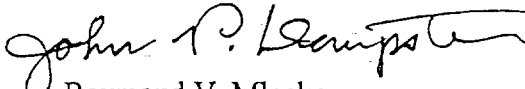
Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,


for Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s

CC: Mr. Brian Brinkley
Director of Radiology
St. Vincent Frankfort Hospital
1300 S. Jackson
Frankfort, IN 46041